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510(k) SUMMARY

K961507

General Information

Date Prepared	April 18, 1996
Classification	Class III
Trade Name	WALLSTENT® Tracheobronchial Endoprosthesis
Common Name	Tracheal Endoprosthesis
Submitter	Schneider (USA) Inc 5905 Nathan Lane Minneapolis, MN 55442 (612) 550-5848
Contact	Cathy Yohnk Senior Regulatory Affairs Associate
Predicate Device	WALLSTENT® Tracheobronchial Prosthesis, K934116· WALLSTENT® Tracheobronchial Prosthesis, K945494

Device Description

The WALLSTENT® Tracheobronchial Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and an elastomeric polymer. Smaller diameter models may utilize a radiopaque core. The prosthesis is a braided wire structure which may be covered with an elastomeric polymer in selected models. The outward radial force along with the ends of the device serve to stabilize the prosthesis after implanted. The prosthesis is offered in covered and uncovered version to allow physicians to select the most appropriate model based on their preference and individual patient condition. The stent's purpose is to increase or maintain the inner lumenal diameter of the tracheobronchial passage.

The stent is placed by means of a delivery system. The delivery system is a coaxial tubing assembly which constrains the prosthesis until it is released in a controlled manner. The release of the stent is accomplished by retracting the outer sheath. The

prosthesis is packaged constrained on the delivery system ready for placement. The system is sterile and intended for single use only.

Indication

The WALLSTENT® Tracheobronchial Endoprosthesis is intended for use in the treatment of tracheobronchial strictures and fistulas produced by malignant neoplasms or in benign strictures and fistulas after all alternative therapies have been exhausted.

Technological Characteristics

This premarket notification deals with modification of the indication for use statement. The design of the endoprosthesis is the same as that of the predicate device.

Summary

In summary Schneider (USA) Inc believes the above listed predicate devices and the WALLSTENT® Tracheobronchial Endoprosthesis are substantially equivalent based on design, materials, methods of fabrication and indications for use.